NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CORCEPT THERAPEUTICS, INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 18-3632 (SDW) (LDW) (Consolidated with Civil Action Nos. 19-5066 and 19-21384) **MARKMAN OPINION** June 23, 2020

WIGENTON, District Judge.

Before this Court are the briefs and supporting materials of Plaintiff Corcept Therapeutics, Inc. ("Plaintiff") and Defendant Teva Pharmaceuticals USA, Inc. ("Defendant") regarding their request for patent claim construction pursuant to Local Patent Rule 4.5(a). This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b) and 1400(b). This Court held a *Markman*[1] hearing on March 5, 2020 regarding patent claims in Plaintiff's U.S. Patent Nos. 8,921,348 ("the '348 Patent") and 9,829,495 ("the '495 Patent").[2] After carefully considering the parties' written and oral arguments, this Court construes the three disputed claim terms as discussed below.

[1] *Markman v. Westview Instruments Inc.*, 52 F.3d 967 (Fed. Cir. 1995).

[2] The '348 Patent and '495 Patent, along with U.S. Patent No. 10,195,214 ("the '214 Patent"), are collectively referred to as the "patents in suit." Subsequent to briefing and prior to the *Markman* hearing, the parties agreed that the disputed terms in the '214 Patent no longer required construction. (D.E. 141.)

I. BACKGROUND

The patents in suit cover methods of administering and using mifepristone, a drug that Plaintiff markets under the brand name Korlym®. (D.E. 110 at 1.)[3] The drug is approved by the U.S. Food and Drug Administration ("FDA") to treat patients with endogenous Cushing's syndrome,[4] specifically to "control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery." (D.E. 114-2 at 82 (2012 Korlym® Label).) Plaintiff asserts that Defendant infringed the patents in suit by filing an abbreviated new drug application ("ANDA"), seeking FDA approval to market a generic version of Korlym® for the same indication. (D.E. 110 at 1.) Plaintiff commenced this lawsuit on March 15, 2018, and the case was later consolidated with Civil Action Nos. 19-5066 and 19-21384. (D.E. 1; *see* D.E. 148 at 1–2.)

II. LEGAL STANDARD

Patent claim construction is a matter of law for the court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). During interpretation of a claim, courts should initially look to intrinsic evidence, namely "the patent claims, the specification and the prosecution history if in evidence." *Bristol-Myers Squibb Co. v. Immunex Corp.*, 86 F. Supp. 2d 447, 448 (D.N.J. 2000). "[I]ntrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "The court should presume that the terms in the claim mean what they say, and,

[3] The facts in this Opinion are generally taken from the parties' Joint Claim Construction and Prehearing Statement (D.E. 110), *Markman* briefs (D.E. 114, 116, 121, 122), and record citations therein.

[4] Cushing's syndrome is a medical condition characterized by excess cortisol levels. (D.E. 114 at 5; D.E. 116 at 1.) The condition can be classified as exogenous or endogenous depending on whether the excess cortisol levels are caused by drugs (exogenous) or by the body itself (endogenous). (D.E. 114 at 5; '495 Patent at 2:19–24.)

unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms." *Bristol-Myers Squibb Co.*, 86 F. Supp. 2d at 448. A person of ordinary skill in the art "is deemed to read the claim term . . . in the context of the entire patent." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005); *see Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history." (citation omitted)); *see also Markman*, 52 F.3d at 979.

If the intrinsic evidence alone will not resolve the ambiguity, the Court may rely on extrinsic evidence, which includes expert testimony, treatises, dictionaries and articles. *Bristol-Myers Squibb Co.*, 86 F. Supp. 2d at 448–49. Extrinsic evidence may not be used to vary or contradict the meaning established by the intrinsic evidence. *Phillips*, 415 F.3d at 1318–19, 1324. "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be . . . the correct construction." *Id.* at 1316.

A key aspect of claim construction is to assist the jury in understanding complicated language and concepts. *See Encap LLC v. Oldcastle Retail, Inc.*, Civ. No. 11-808, 2012 WL 2339095, at *9 (E.D. Wis. June 19, 2012) ("Claim construction is not intended to allow for needless substitution of more complicated language for terms easily understood by a lay jury."); *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1247 (Fed. Cir. 2001) ("It is critical for trial courts to set forth an express construction of the material claim terms in dispute, in part because the claim construction becomes the basis of the jury instructions, should the case go to trial. It is also the necessary foundation of meaningful appellate review." (citation omitted)).

III. ANALYSIS[5]

The parties dispute the meanings of three claim terms with respect to the patents in suit. The disputed terms are: (1) "achieve mifepristone blood levels greater than 1300 ng/mL," as used in claim 1 of the '348 Patent; (2) "a method of concurrently treating Cushing's syndrome and differentially diagnosing adrenocorticotropic hormone (ACTH)-dependent Cushing's syndrome," as used in claim 1 of the '495 Patent; and (3) "a method of concurrently treating Cushing's syndrome and obtaining a measurement indicative of differential diagnosis of adrenocorticotropic hormone (ACTH)-dependent Cushing's syndrome," as used in claim 18 of the '495 Patent. For the reasons discussed below, this Court gives each term its plain and ordinary meaning, *i.e.*, no construction is required.

A. The '348 Patent

"achieve mifepristone blood levels greater than 1300 ng/mL"		
Plaintiff's Proposed Construction	**Defendant's Proposed Construction**	**Court's Construction**
"ensure mifepristone blood levels remain greater than 1300 ng/mL"[6]	Plain and ordinary meaning; no construction required. Alternatively, plain and ordinary meaning, which is: "ensure that the patient's mifepristone blood levels are greater than 1300 ng/mL"	Plain and ordinary meaning; no construction required.

[5] Claims are construed from the vantage point of a person of ordinary skill in the art ("POSA") at the time of the invention. *Phillips*, 415 F.3d at 1313. Thus, for each patent, before this Court can review the bounds of the claims in light of the specification, it must establish the level of skill that a POSA possessed at the time of the invention. *AllVoice Computing PLC v. Nuance Commc'ns, Inc.*, 504 F.3d 1236, 1240 (Fed. Cir. 2007). Here, the parties agree that a POSA for purposes of the '348 Patent would typically have either a Pharm.D. or a Ph.D. in organic chemistry, pharmacology, or a related discipline; or an M.D. or a Bachelor's or Master's degree in organic chemistry or a related field with at least four years of experience relating to the study of pharmacokinetics or dosing of drugs, their detection and quantification, or their metabolism. (*See* D.E. 115 (Excerpts from Corcept's Responses to Teva's Invalidity Contentions).) Similarly, for the '495 Patent, the parties agree that a POSA would typically be an endocrinologist with at least an M.D. degree and a few years of experience in treating patients with Cushing's syndrome and/or researching treatments for Cushing's syndrome. (*See id.*) This Court will, therefore, adopt the parties' definitions.

[6] Plaintiff's originally proposed construction was "ensure mifepristone blood levels remain greater than 1300 ng/mL *during treatment*." (D.E. 116 at 6 (emphasis added).) However, during the *Markman* hearing, Plaintiff withdrew the "during treatment" limitation. (D.E. 145 at 24.)

The '348 Patent is directed to optimizing the blood "levels of mifepristone in a patient suffering from a mental disorder amenable to treatment by mifepristone." ('348 Patent at Abstract.)[7] According to the patent, "administration of the same dose of mifepristone can produce widely varying blood serum levels in different patients." (*Id.* at 1:28–30.) "The varied blood serum levels can result in some patients not receiving an efficacious dose of mifepristone." (*Id.* at 1:30–32.) The inventor claims to have discovered that mifepristone blood levels generally need to exceed 1300 ng/mL for the drug to be more effective than a placebo. (*See id.* at 5:53–56.) This alleged discovery is embodied in the patent's sole independent claim, which recites a method for optimizing a patient's mifepristone levels by, *inter alia*, "adjusting the daily dose of the patient to achieve mifepristone blood levels greater than 1300 ng/mL." (*Id.* at 16:34–35.)

The parties dispute whether the term "achieve mifepristone blood levels greater than 1300 ng/mL" requires that the patient's blood levels "remain" greater than 1300 ng/mL (Plaintiff's construction), or that the patient's blood levels merely exceed 1300 ng/mL (Defendant's construction). (D.E. 114 at 16; D.E. 116 at 5.) Although the plain language of the term does not specify a duration,[8] Plaintiff argues that such a requirement is supported by the patent's specification and prosecution history. (D.E. 116 at 6–9.) This Court disagrees.

Plaintiff points to two instances where the specification refers to the "present invention" in connection with mifepristone blood levels "remain[ing]" greater than 1300 ng/mL, and argues that this language limits the claims. (*See* '348 Patent at 2:57–61, 6:11–14); *see also Verizon Servs.*

[7] Although the specification of the '348 Patent focuses on treating mental disorders, claim 1 is written more broadly, referring to any disorder that is "amenable to treatment by mifepristone." ('348 Patent at 16:27–28.)

[8] The word "achieve" is a synonym for "accomplish" or "attain" and does not imply any temporal limitation on how long the result must be "accomplished" or "attained." *See The American Heritage College Dictionary* 11 (3d ed. 1993). For an example of plain and ordinary usage, consider a scholarship requiring that a student "achieve" a 3.0 GPA as opposed to "maintain" a 3.0 GPA. The former suggests a one-time scholarship without future obligations, while the latter suggests a continuing scholarship subject to a continuing obligation.

Corp. v. Vonage Holdings Corp., 503 F.3d 1295, 1308 (Fed. Cir. 2007) ("When a patent thus describes the features of the 'present invention' as a whole, this description limits the scope of the invention." (citations omitted)). However, "the standard for disavowal is exacting, requiring clear and unequivocal evidence that the claimed invention includes or does not include a particular feature." *Poly-Am., L.P. v. API Indus., Inc.*, 839 F.3d 1131, 1136 (Fed. Cir. 2016) (citations omitted). Thus, "[w]hen consulting the specification to clarify the meaning of claim terms, courts must not import limitations into the claims from the specification. . . . unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exc[lus]ion or restriction." *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1352 (Fed. Cir. 2010) (internal quotation marks and citations omitted); *see also Verizon Servs.*, 503 F.3d at 1309 (rejecting appellant's attempt to import a limitation from the specification into the claim because the specification made reference to the limitation only "on occasion" and because the appellant failed "to identify language that would require" the proposed limitation "in every case").

Here, the specification contains other descriptions of the "present invention" that do not include the word "remain." (*See, e.g.*, '348 Patent at Abstract, 1:40–2:5, 2:62–3:5.) In fact, it also describes "the present invention" as "provid[ing] a method for optimizing levels of mifepristone in a patient suffering from a *mental disorder* amenable to treatment by mifepristone," a restriction that Plaintiff does not seek to import to the claims. (*Id.* at 1:40–43 (emphasis added).) It thus lacks the clear manifestation required to exclude or restrict the claims with respect to the duration of mifepristone blood levels greater than 1300 ng/mL.[9]

[9] Plaintiff's cited examples also evidence that the patentee knew how to specify that the mifepristone blood levels "remain" at a certain threshold, when it wished to do so. This Court will therefore respect the patentee's choice to omit the word "remain" from the claims and enjoy the resulting broader claims scope. *See Novartis Pharm. Corp. v. Actavis, Inc.*, Civ. No. 12-366, 2013 WL 6142747, at *10 (D. Del. Nov. 21, 2013).

Plaintiff also repeatedly emphasizes that the invention's "purpose" can guide claim construction, and that mifepristone levels must remain in the efficacious range to treat Cushing's syndrome. (*See* D.E. 116 at 7–8 (citations omitted).) However, the claims are not directed specifically to a method of treating patients suffering from Cushing's syndrome and Cushing's syndrome is not even mentioned in the specification. As stated in the preamble of the patent's only independent claim, the purpose of the invention is to treat "patient[s] suffering from a disorder amenable to treatment by mifepristone." ('348 Patent at 16:27–28; *see also id.* at Abstract ("The present invention provides a method for optimizing levels of mifepristone in a patient suffering from a mental disorder amenable to treatment by mifepristone.").) Regardless, "it is generally not appropriate to limit claim language to exclude particular devices because they do not serve a perceived 'purpose' of the invention." *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1325 (Fed. Cir. 2008) (citation and quotation marks omitted).[10]

"When claim language has a plain meaning on an issue as the language does here, leaving no genuine uncertainties on interpretive questions relevant to the case, it is particularly difficult to conclude that the specification reasonably supports a different meaning." *Straight Path IP Grp., Inc. v. Sipnet EU S.R.O.*, 806 F.3d 1356, 1361 (Fed. Cir. 2015). This Court therefore concludes that no construction is necessary and declines to add Plaintiff's proposed limitation to the claim term.

[10] Nor is it appropriate to take a single statement made during prosecution of a parent application to restrict the claims of a child patent. *See Verizon Servs.*, 503 F.3d at 1306 (Fed. Cir. 2007) ("To operate as a disclaimer, the statement in the prosecution history must be clear and unambiguous, and constitute a clear disavowal of scope." (citation omitted)). Thus, a statement from the applicant during prosecution of the '348 Patent's parent application—that "the present invention surprisingly discovered that maintaining mifepristone serum levels above 1300 ng/mL provide[s] an effective treatment"—is not sufficient to add a temporal limitation to the disputed claim term. (*See* D.E. 116 at 8–9.)

B. The '495 Patent

"a method of concurrently treating Cushing's syndrome and differentially diagnosing adrenocorticotropic hormone (ACTH)-dependent Cushing's syndrome" **"a method of concurrently treating Cushing's syndrome and obtaining a measurement indicative of differential diagnosis of adrenocorticotropic hormone (ACTH)-dependent Cushing's syndrome"**		
Plaintiff's Proposed Constructions	**Defendant's Proposed Constructions**	**Court's Constructions**
"a method of concurrently treating Cushing syndrome and [differentially diagnosing adrenocorticotropic hormone (ACTH)-dependent Cushing's syndrome / obtaining a measurement indicative of differential diagnosis of adrenocorticotropic hormone (ACTH)-dependent Cushing's syndrome] in order to recommend transphenoidal surgery or appropriate imaging to identify source of the ectopic ACTH secretion"	Plain and ordinary meaning; no construction required. Alternatively, plain and ordinary meaning, which is: "a method of concurrently treating Cushing's syndrome and [distinguishing between different types of ACTH-dependent Cushing's syndrome / obtaining a measurement to distinguish between different types of ACTH-dependent Cushing's syndrome]"	Plain and ordinary meaning; no construction required.

One subtype of endogenous Cushing's syndrome is ACTH-dependent Cushing's syndrome, which is characterized by the excessive secretion of adrenocorticotropic hormone, or ACTH, which causes the adrenal glands to produce excess cortisol. ('495 Patent at 1:23–24, 2:24–29.) The '495 Patent discloses a method to differentially diagnose (*i.e.*, distinguish) between two types of ACTH-dependent Cushing's syndrome: Cushing's Disease, which is caused by an ACTH-secreting tumor in the pituitary gland, and ectopic ACTH syndrome, which is caused by an ACTH-secreting tumor outside the pituitary gland. (*Id.* at 2:30–35, 15:64–67.)

The '495 Patent contains two independent claims, and the parties dispute whether the preambles of these claims should be given their plain and ordinary meaning or be restricted to a particular purpose: "in order to recommend transphenoidal surgery or appropriate imaging to

identify source of the ectopic ACTH secretion." (D.E. 114 at 7–8; D.E. 116 at 11–12.)[11] Although the terms' plain language does not include a restriction as to purpose, Plaintiff argues that such a restriction is supported by the patent's specification. (D.E. 116 at 12–14.) This Court disagrees.

Plaintiff points to one sentence from the '495 Patent to support its argument that the purpose of the differential diagnosis is to recommend transphenoidal surgery (in the case of Cushing's Disease) or appropriate imaging (in the case of ectopic ACTH syndrome). (D.E. 116 at 13 (quoting '495 Patent at 2:35–39 ("Correct differential diagnosis between the Cushing Disease and ectopic ACTH syndrome is important for endocrinologists to recommend transphenoidal surgery or appropriate imaging to identify [the] source of the ectopic ACTH secretion.")).)

As discussed in connection with the '348 Patent, although an invention's "purpose" can guide claim construction, "courts must not import limitations into the claims from the specification. . . . unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exc[lus]ion or restriction." *Trading Techs.*, 595 F.3d at 1352 (internal quotation marks and citations omitted). Plaintiff's cited sentence does not rise to the level of manifest exclusion or restriction. The sentence on its face states that recommending surgery or imaging is an "important" purpose of differential diagnosis, not that it is the *only* purpose. Nothing in the specification or claim language restricts the claims from encompassing differential diagnosis for the purpose of recommending other treatment options. *See Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1256 (Fed. Cir. 2011) ("Where a specification does not require a limitation, that limitation should not be read from the specification into the claims." (citation and quotations marks omitted)). This Court will therefore give the disputed terms their plain and ordinary meanings. *See Warner Chilcott Co. v. Mylan Inc.*, Civ.

[11] Transphenoidal surgery is a type of surgery used to remove tumors of the pituitary gland. (D.E. 116 at 11 n.6.)

No. 11-6844, 2013 WL 3336872, at *3 (D.N.J. July 2, 2013) (giving a disputed claim term its plain and ordinary meaning where neither party could establish that construction was "necessary").

IV. CONCLUSION

For the reasons stated above, this Court construes the disputed claims as set forth in this Opinion. An appropriate order follows.

s/ Susan D. Wigenton
Susan D. Wigenton, U.S.D.J.

Orig: Clerk
cc: Leda Dunn Wettre, U.S.M.J.
Parties